IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DWYN HARBEN,	:	
	:	
Plaintiff,	:	
	:	**CIVIL ACTION**
v.	:	
	:	**NO. 18-1833**
ALLERGAN USA, INC., et al.,	:	
	:	
Defendants.	:	

ORDER

AND NOW, this ___15th____ day of July, 2019, upon consideration of Defendant's Motion to Dismiss ("Motion") (Doc. 6), Plaintiff's Response in Opposition (Doc. 15), and Defendant's Sur-Reply (Doc. 23), **IT IS HEREBY ORDERED AND DECREED** that Defendant's Motion is **DENIED IN PART** and **GRANTED IN PART**.[i]

IT IS FURTHER ORDERED that Count IV: Strict Products Liability-Manufacturing Defect and Count V: Breach of Implied Warranty of Merchantability are **DISMISSED WITH PREJUDICE**.

BY THE COURT:

/s/ Petrese B. Tucker

Hon. Petrese B. Tucker, U.S.D.J.

I. FACTUAL AND PROCEDURAL BACKGROUND

Before the Court is Defendants' Allergan USA, Inc., Allergan Sales, LLC and Allergan, Inc. (collectively "Defendants") Motion to Dismiss Plaintiff Dwyn Harben's ("Plaintiff") claims pursuant to Federal Rule of Civil Procedure 12(b)(6), failure to state a claim.

On January 29, 2015, Plaintiff underwent a prophylactic left breast mastectomy and Plaintiff's surgeon implanted the SERI Mesh in Plaintiff's left breast. Compl. ¶ 2, Doc. 1-1. Plaintiff allegedly suffered various complications because of the SERI Mesh and her surgeon removed the mesh on December 28, 2016. Pl.'s Resp. to Defs.' Mot. to Dismiss 1, Doc. 16-1.

The SERI Mesh, manufactured by Defendants, is a "silk-derived biological mesh product intended for use in breast and abdominal surgeries to repair and replace soft tissue deficiencies." Compl. ¶ 26, Doc. 1-1. SERI Mesh is bioresorbable and "facilitates the generation of native, well-vascularized tissue that is twice as thick as the mesh after 24 months." Compl. ¶ 28.

On November 6, 2017, Plaintiff filed this strict liability and negligence action in the Philadelphia Court of Common Pleas. Notice of Removal ¶ 2, Doc. 1. Defendants removed to this Court on May 2, 2018. Notice of Removal, Doc. 1. Plaintiff argues that Defendants manufactured, designed, distributed, marketed, sold and warranted the defective SERI Mesh. Compl. ¶ 1. Plaintiff seeks recovery for physical pain and mental anguish she suffered due to the defective SERI Mesh. Compl. ¶ 207.

II. STANDARD OF REVIEW

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a plaintiff must plead sufficient factual matter to show that relief is plausible. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A claim is plausible when a "plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. The plausibility determination is context specific, thus, the court must rely on its own judicial experience and common sense. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009).

The Court must take a plaintiff's well pleaded facts as true and view them in the light most favorable to the plaintiff. *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008). The "complaint must do more than allege the plaintiff's entitlement to relief," it must "show such [] entitlement with its facts." *Fowler*, 578 F.3d at 211. As such, "[t]hreadbare recitals of the . . . cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678.

III. DISCUSSION

Plaintiff voluntarily withdrew count II-strict liability failure to warn, count III-strict liability design defect, and count VIII-violations of Pennsylvania's unfair trade practices and consumer protection law. Pl.'s Resp. to Defs.' Mot. to Dismiss 1 n.2, Doc. 15-1. The Court will address the remaining claims—negligence and negligent misrepresentation, strict liability-manufacturing defect, breach of the implied warranty of merchantability, and breach of express warranty—in turn.

A. Negligence and Negligent Misrepresentation Claims

i. Plaintiff's Negligence Claims are not Barred by the Learned Intermediary Doctrine

Defendants argue that Plaintiff's negligence claims are barred by the learned intermediary doctrine because Plaintiff's only cognizable claim is failure to warn. Defs.' Mot. to Dismiss Mem. 10, Doc. 6-1. This proposition is incorrect.

In Pennsylvania, under the learned intermediary doctrine, a manufacturer has a duty to warn the prescribing physician—the learned intermediary—of the dangers associated with the medical device, not the patient or the public. *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 749 (W.D. Pa. 2004). Plaintiff's negligence claims are not barred by the learned intermediary doctrine as Plaintiff has pled that Defendants failed to provide Plaintiff's

surgeon with information relating to the risks and safety concerns of the SERI Mesh, not Plaintiff and the general community. Compl. ¶¶ 56, 59, 62.

ii. Plaintiff Sufficiently Pled Her Negligence Claim

Plaintiff argues that "Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the SERI Mesh." Compl. ¶ 129, Doc. 1-1. Plaintiff further argues that at the time of the manufacture and sale of the SERI Mesh, Defendants knew or should have known that "using the SERI Mesh in its intended use or in a reasonably foreseeable manner" created various significant risks such as "mesh/implant loss." Compl. ¶ 132.

To prevail on a negligent design and manufacturing action in Pennsylvania, a plaintiff must show that (1) "the defendant had a duty to conform to a certain standard of conduct," (2) "the defendant breached that duty," (3) "that [] breach caused the injury in question," and (4) "actual loss or damage." *Phillips v. Cricket Lighters*, 841 A.2d 1000, 1008 (Pa. 2003).

It is undisputed that Defendants manufactured the SERI Mesh, thus they owed a duty of care to Plaintiff, the recipient of the SERI Mesh. Plaintiff argues that Defendants breached that duty when it placed SERI Mesh on the market after the FDA determined that the SERI Mesh was not "cleared or approved for use in breast reconstruction using a tissue expander or implant." Compl. ¶ 80, Doc. 1-1. Furthermore, Plaintiff argues, after releasing the SERI Mesh Defendants received "adverse event reports from healthcare providers reporting complications associated with the SERI Mesh implanted in the breast." Compl. ¶ 53, Doc. 1-1.

Plaintiff's surgeon removed the SERI Mesh less than twenty-four months after it was originally implanted. Compl. ¶ 92. Prior to the removal surgery, Plaintiff's breast "appear[ed]

discolored and was puffing out/blistering," and she suffered "a small opening [on] her mastectomy scar line." Compl. ¶¶ 87, 89. During the SERI Mesh removal surgery, Plaintiff's surgeon "identified partially dissolved SERI Mesh . . . that had not bioresorbed," and her surgeon excised small amounts of [SERI] Mesh Compl. ¶¶ 87, 92. These allegations, taken as true, show that Plaintiff has sufficiently pled elements two—breach of duty—and three—proximate cause of Plaintiff's injuries. Reviewing the facts in the light most favorable to Plaintiff, the Court finds that Plaintiff has pled sufficient facts to show that relief on the negligence claim is plausible.

iii. Plaintiff Sufficiently Pled Her Negligent Misrepresentation Claim

To prevail on a negligent misrepresentation claim, a plaintiff must show "1) a misrepresentation of a material fact; 2) made under the circumstances in which the misrepresenter ought to have known its falsity; 3) with an intent to induce another to act on it; and 4) which results in injury to a party acting in justifiable reliance on the misrepresentation." *Bortz v. Noon*, 729 A.2d 555, 561 (Pa. 1999). Furthermore, "there must be an existence of a duty owed by one party to another." *Id.*

Plaintiff alleges that "Defendants negligently provided Plaintiff, Plaintiff's health care providers, and the general [] community with false or incorrect information or omitted or failed to disclose material information concerning [the] SERI Mesh['s] . . . safety, efficacy, failure rate and approved uses . . . . " Compl. ¶ 182. Defendants argue that this claim must be dismissed as it is a "recasting of Plaintiff's deficient failure to warn claim," which cannot be asserted in Pennsylvania. Defs.' Mot. to Dismiss Mem. 9–10, Doc. 6-1. Furthermore, Defendants argue, their "duty to warn extends only to the physician, not Plaintiff or the general healthcare community." Defs.' Mot. to Dismiss Mem. 10. (emphasis omitted).

Plaintiff counters that Pennsylvania courts recognize negligent misrepresentation claims in medical device cases. Pl.'s Resp. to Mot. to Dismiss 9, Doc. 15-1. Plaintiff avers that her misrepresentation claims are based on the following grounds. First, Defendants "misrepresented the safety and effectiveness of the SERI Mesh when used in breast surgeries through both affirmative representations and omissions." Pl.'s Resp. to Defs.' Mot. to Dismiss 10, Doc. 15-1. Second, "Defendants misrepresented the approved uses cleared by the FDA when they knew . . . [the] unapproved uses were neither safe nor effective." Pl.'s Resp. to Defs.' Mot. to Dismiss 10.

Plaintiff's negligent misrepresentation claim is not a "recast" of Plaintiff's strict liability failure to warn claim. Plaintiff described in detail the various marketing and promotional tools Defendants used–live videos of surgeons implanting the SERI Mesh, a dedicated website, pamphlets and brochures, printed advertising materials and detailed testimonials from surgeons that implanted the SERI Mesh. Compl. ¶¶ 56–58, 60–62, Doc. 1-1. Plaintiff's surgeon "reviewed [the] marketing and labeling materials regarding [the] SERI Mesh, which were created and distributed by Defendants," and relying on Defendants' materials, Plaintiff's surgeon recommended to Plaintiff the SERI Mesh, and later implanted it. Compl. ¶¶ 59, 70. Furthermore, Plaintiff alleges, Defendants intentionally concealed the risks associated with the SERI Mesh despite reports of complications, and warnings from the FDA. Compl. ¶¶ 52, 74–84. Defendants, Plaintiff argues, misled surgeons and consumers to believe that the SERI Mesh was intended for breast reconstruction and the SERI Mesh would replace soft tissue and boiresorb in twenty-four months. Compl. ¶ 63. Plaintiff's surgeon removed the SERI Mesh less than twenty-four months after it was implanted. Compl. ¶ 92, Doc. 1-1. The SERI Mesh partially dissolved and caused Plaintiff to suffer "chronic

inflammation and histiocytic/foreign body giant cell reaction to polarizable foreign material." Compl. ¶ 92. Plaintiff has since undergone numerous revision procedures to remove a mass and reconstruct her breast. Plaintiff remains at risk for further complications stemming from the SERI Mesh. Compl. ¶¶ 93–95. Taking these allegations as true, the Court finds that Plaintiff has sufficiently pled her negligent misrepresentation claim.

B. Comment k Bars Plaintiff's Strict Liability-Manufacturing Defect Claim and Breach of Implied Warranty of Merchantability Claim

i. Strict Liability-Manufacturing Defect Claim Must Be Dismissed

Plaintiff alleges that "[a]s a direct and proximate result of the manufacturing defects of [the] SERI Mesh, Plaintiff [] suffered and will continue to suffer serious physical injuries []." Compl. ¶ 163, Doc. 1-1. Defendants argue that pursuant to comment k § 402A of the Restatement (Second) of Torts, Pennsylvania does not permit recovery in strict liability for prescription medical devices. Defs.' Mot. to Dismiss Mem. 4, Doc. 6-1. Defendants aver that the SERI Mesh is a prescription medical device, and by its nature, a prescription medical device is unavoidably unsafe and not subject to strict liability claims. Defs.' Mot. to Dismiss Mem. 4.

Pennsylvania follows § 402A of Restatement (Second) of Torts' strict liability analysis. *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 348 (Pa. 2014). It follows that "one who sells a product in a defective condition unreasonably dangerous to the user or consumer . . . is subject to liability for physical harm . . . caused." *Barnish v. KWI Bldg. Co.*, 980 A.2d 535, 541 n.4. (Pa. 2009). To bring a strict product liability claim under § 402A, plaintiff must show that (1) the product was defective, (2) the defect caused the plaintiff's injury, and (3) the defect existed at the time the product left the manufacturer's control. Restatement (Second) of Torts § 402A. The theory of liability in this case is premised on the applicability

of comment k of § 402A to prescription medical devices. Comment k "denies [the] application of strict liability [on] products such as *prescription drugs*, which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings." *Hahn v. Richter*, 673 A.2d 888, 889–90 (Pa. 1996) (emphasis added).

Since *Hahn*, the Pennsylvania Supreme Court has not ruled on the applicability of comment k to prescription medical devices. Being that no decision exists, this Court must predict how the Pennsylvania Supreme Court would rule in the event it addresses this issue. *Berrier v. Simplicity Mfg. Inc.*, 563 F.3d 38, 45–46 (3d Cir. 2009) ("In the absence of controlling decision by the Pennsylvania Supreme Court, a federal court applying that state's substantive law must predict how Pennsylvania's highest court would decide this case."). To aid in its review, a federal court "must consider relevant state precedents, analogous decisions, considered dicta . . . [] and other reliable data tending convincingly to show how the highest court in the state would decide the issue at hand." *McKenna v. Ortho Pharm. Corp.*, 622 F.2d 657, 663 (3d Cir. 1980).

In 2006, the Pennsylvania Superior Court held that a plaintiffs' strict liability claim against a prescription medical device manufacturer was barred by comment k. *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2006). The court found "no reason why the same rational [sic] applicable to prescription drugs may not be applied to medical devices." *Id*. Courts in this District, relying on *Hahn* and *Creazzo*, have predicted that the Pennsylvania Supreme Court will extend comment k to prescription medical devices. *See, e.g., Esposito v. I-Flow Corp.*, No. 10-3883, 2011 U.S. Dist. LEXIS 122570 (E.D. Pa. Oct. 24, 2011);

Soufflas v. Zimmer, Inc., 474 F. Supp. 2d 737, 750 (E.D. Pa. 2007); *Davenport v. Medtronic, Inc.*, 302 F. Supp. 2d 419 (E.D. Pa. 2004); *Taylor v. Danek Medical, Inc.*, No. 95-7232, 1998 U.S. Dist. LEXIS 20265 (E.D. Pa. Dec. 29, 1998). Considering the decisions of courts in this Circuit and the lower court in Pennsylvania, this Court predicts the Pennsylvania Supreme Court will extend comment k to prescription medical devices. Thus, Plaintiff's strict liability-manufacturing defect claim must be dismissed.

ii. Breach of the Implied Warranty of Merchantability Claim Is Dismissed

The implied warranty of merchantability "protect[s] buyers from loss where goods purchased are below commercial standards." *Barton v. Lowe's Home Ctrs., Inc.*, 124 A.3d 349, 357 (Pa. Super. Ct. 2015). Goods need not be of the best quality, but "should . . . be of reasonable quality within [the] expected variations and for the ordinary purpose for which they are used." *Id.* at 358.

Plaintiff alleges that at the time Plaintiff purchased the SERI Mesh, it was not in merchantable condition. Compl. ¶ 177, Doc. 1-1. Defendants argue that this claim "must fail for the same reason that Plaintiff's strict liability claims fail." Defs.' Mot. to Dismiss Mem. 8, Doc. 6-1. Comment k, Defendants argue, does not recognize a claim for breach of implied warranty for medical devices. Defs.' Mot. to Dismiss Mem. 8.

As stated above in Section B.i., the Pennsylvania Supreme Court has not ruled on the applicability of comment k to prescription medical devices. As such, the Court must also predict how the Pennsylvania Supreme Court would decide a breach of warranty claim in this instance.

In *Makripodis v. Merrell-Dow Pharms.*, the Pennsylvania Superior Court upheld the trial court's dismissal of plaintiff's implied warranty of merchantability claim against a

prescription drug manufacturer. *Makripodis v. Merrell-Dow Pharms.*, 523 A.2d 374, 377 (Pa. Super. Ct. 1987). The court held that "the very nature of prescription drugs themselves precludes the imposition of a warranty of fitness for 'ordinary purposes.'" *Id*. Prescription drugs, the court stated, can only be obtained via a prescription, and that "restriction . . . has been imposed because of the inherently dangerous properties of such drugs." *Id*. at 376. Courts in this Circuit, relying on *Makripodis*, have concluded that comment k is equally applicable to strict liability and breach of implied warranty. *Terrell v. Davol, Inc.*, No. 13-5074, 2014 U.S. Dist. LEXIS 103695, *21 (E.D. Pa. July 30, 2014); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 491 n.35 (W.D. Pa. 2012); *Soufflas*, 474 F. Supp. 2d at 752; *Murray v. Synthes (U.S.A.), Inc.*, No. 95-7796, 1999 U.S. Dist. LEXIS at * 28 (E.D. Pa. Aug. 23, 1999).

In *Parkinson*, the court stated that "there is no basis in law or logic to treat prescription drugs differently than prescription medical devices." *Parkinson*, 315 F. Supp. 2d at 753. The court further concluded that since "breach of implied warranty claims for prescription drugs are precluded under Pennsylvania law, breach of implied warranty claims for medical devices [] are precluded for identical reasons." *Id*. The Court agrees with the consensus that the Pennsylvania Supreme Court would extend comment k to breach of implied warranty of merchantability claims. Accordingly, Plaintiff's breach of implied warranty claim is dismissed.

C. Breach of Express Warranty Claim

i. Plaintiff Sufficiently Pled Her Breach of Express Warranty Claim

Express warranties are "specifically negotiated;" they are created by a seller through "any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain." *Goodman v. PPG Indus.*, 849 A.2d

1239, 1243 (Pa. Super. Ct. 2004); 13 Pa. Cons. Stat. Ann. § 2313. Specifically, Express warranties can be created in three ways:

> 1) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an **express warranty** that the goods shall conform to the affirmation or promise.
> 2) Any description of the goods which is made part of the basis of the bargain creates an **express warranty** that the goods shall conform to the description.
> 3) Any sample or model which is made part of the basis of the bargain creates an **express warranty** that the whole of the goods shall conform to the sample or model.

13 Pa. Cons. Stat. Ann. § 2313 (emphasis added).

Defendants argue that Plaintiff's "claim must be dismissed because she [] failed to plead essential elements of the claim." Defs' Mot. to Dismiss Mem. 13, Doc. 6-1. Here, Plaintiff alleges that in their marketing materials, and instructions regarding the SERI Mesh, Defendants expressly represented that the "SERI Mesh was safe, well-tolerated, efficacious, and fit for their intended purpose and was of marketable quality." Compl. ¶ 176, Doc. 1-1. Plaintiff's surgeon allegedly reviewed the marketing materials Defendants published. Compl. ¶ 59, Doc. 1-1. Additionally, Plaintiff alleged various declarations that Defendants published on its website. Compl. ¶¶ 60–62. Defendants' FAQ page listed breast revision surgeries as a procedure in which the SERI Mesh may be used; the website also included a surgeon experience section with reviews from different surgeons who utilized the SERI Mesh; Defendants also uploaded videos of live surgeries where surgeons implanted the SERI Mesh. Compl. ¶¶ 60–62. Defendants' website allegedly state that the SERI Mesh had bioreplacement characteristics and it generated "native, well-vascularized tissue" in twenty-four months, but as early as three months. Compl. ¶¶ 63–64. Taking these facts as true, Plaintiff has sufficiently pled that in its marketing of the SERI Mesh, Defendants made

various affirmations or promises regarding the SERI Mesh's success, which Plaintiff's surgeon studied and reviewed prior to implanting the SERI Mesh. Thus, the breach of express warranty claim will not be dismissed.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss is DENIED IN PART and GRANTED IN PART.